DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Drew Johnson
Director, Regulatory Affairs
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Dr., St. 100
Plano, TX 75024

FEB 25 2000

Dear Mr. Johnson:

On June 16, 1999, we received a Section 513(f) Petition proposing reclassification of the Totally Implanted Spinal Cord Stimulator for Pain Relief from class III to class II. A subsequent panel meeting regarding the reclassification of this device was held on September 17, 1999. At this meeting, presentations were made both in support of reclassification and against reclassification. At the conclusion of the panel meeting the panel voted five to one in favor of reclassification of the Totally Implanted Spinal Cord Stimulator for Pain Relief from class III to class II.

The purpose of this letter is to provide you an update on the status of your reclassification petition. FDA has been reviewing the information presented in your petition, comments presented to the petition, the information presented at the panel meeting, and the panel's recommendations. We are using this information as the basis for determining the appropriate classification of these devices.

The agency has been provided with enough information to move forward toward a final decision. As such, the agency believes there may be available special controls to ensure the safety and effectiveness of this type of device. A decision has not yet been reached.

Sincerely,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DOP-0788

LET2